DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
D 1427 B

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 12, 1998

WARNING LETTER
CHI-11-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Georgia Reger, DVM
Reger Veterinary Clinic
8020 N. Illinois Rte. 159
Caseyville, IL 62232

Dear Dr. Reger:

An investigation of your association with [ ] by Investigator Frederic French of the Food and Drug Administration on September 11, 1997, revealed the illegal purchase, holding and sale of veterinary prescription drugs. You caused these violations in that you failed to establish controls to assure that prescription veterinary drugs which [ ] ordered through authority of your veterinary license are sold only upon the written or other order of a licensed veterinarian based upon a valid veterinarian/client/patient relationship (VCPR). Such purchase, holding, and sales are serious violations of Sections 502(f)(1) and 503(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

These prescription veterinary drugs are misbranded while held for sale after shipment in interstate commerce because they have lost their exemption from the requirement to bear adequate directions for use set forth in Title 21, Code of Federal Regulations, Part 201.105. These prescription veterinary drugs fail to bear adequate directions for use in accordance with Section 502(f)(1). Adequate directions for use means adequate directions for lay use. A prescription veterinary drug, one labeled "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," is a drug which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, and is a drug for which lay use cannot be written.

Prescription veterinary drugs are exempted from the statutory requirement for adequate directions for lay use only when they are in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used by or on the prescription or other order of a licensed veterinarian; or are in the possession of a retail distributor, hospital, or clinic, or other person authorized under state law to dispense veterinary prescription drugs, who is regularly and lawfully engaged in dispensing drugs that are to be used only by or on the prescription or other order of a licensed veterinarian in accordance with the requirements in Title 21, Code of Federal Regulations, Part 201.105 prescribed in Section 503(f)(1) of the Act.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be all inclusive. You, as a responsible associate of the firm and as a licensed veterinarian, have responsibilities to insure that all drugs intended for veterinary use which bear the veterinary prescription legend "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," are dispensed or sold by your firm on the prescription or other order of a licensed veterinarian based upon a valid VCPR.

A valid VCPR is defined by the American Veterinary Medical Association, as the following:

> An appropriate veterinarian/client/patient relationship will exist when: (1) the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animals(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when (2) there is sufficient knowledge of the animals(s) by the veterinarian to initiate at least a general preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animals(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

You should notify this office in writing within 15 working days of receipt of this letter the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to the Food and Drug Administration attention, Paul Boehmer, Compliance Officer.

Sincerely,

Raymond V. Mlecko
District Director

Enclosure